Mycotoxins Testing

Mycotoxins are toxic metabolites produced by certain fungi that can infect and proliferate on various agricultural commodities in the field and/or during storage. Aflatoxin and Ochratoxin are both metabolic byproducts produced by certain Aspergillus molds and are classified as mycotoxins. Aflatoxins may occur as a result of mold growth in a number of susceptible commodities. Aflatoxins (i.e., Aflatoxin B1, B2, G1 and G2) are all toxic by-products of mold growth on certain agricultural commodities. Ochratoxin A is a fungal metabolite produced by certain species of the genera Aspergillus and Penicillium.

Based on a 2022 analysis of *Aspergillus* failures in flower, and information gathered from states across the nation, we anticipate less than 0.05% of all samples will fail for the presence of mycotoxins. Though this is an incredibly low percentage, it is critical to test for mycotoxins because of their potential as carcinogens.

As of December 1, 2022, the Cannabis Regulatory Agency (CRA) requires products that have failed for *Aspergillus* to be tested for mycotoxins prior to submitting a request for remediation per the following rules:

R. 420.305 Testing; laboratory requirements.

Rule 5. (3)(h) Mycotoxins screening if requested by the agency.

R 420.306 Testing marihuana product after failed initial safety testing and remediation.

Rule 6. (3) Products that failed testing for *Aspergillus* may be remediated after subsequent testing for mycotoxins in accordance with R 420.305(3)(h).

Frequently Asked Questions

- a. Would it be possible for the CRA to provide language that communicates why subsequent mycotoxins testing is important?
 - It is required by rule and proper request of the CRA as of December 1, 2022. Additionally, mycotoxins pose a danger to consumers (e.g. carcinogenic, associated with various diseases humans).
- b. Do safety compliance facilities (SCFs) need to collect another sample to test for mycotoxins, or can we use the original sample?
 - SCFs can use the retain from the original sample taken, if enough remains. If there is not enough of the original sample remaining, laboratories can obtain an additional sample of the product; it is only necessary to take enough sample to run the mycotoxins test.
- c. When exactly are tests for mycotoxins required to be run?

Testing for mycotoxins must be run whenever there is an *Aspergillus* failure.

d. If a sample fails for *Aspergillus*, would the licensee who owns the sample retest for mycotoxins and then send in a remediation request?

Yes. Mycotoxins testing is required before remediation. Anything that fails for *Aspergillus* will not be approved for remediation unless it has passed mycotoxins testing.

e. Does the mycotoxins testing requirement pertain to all flower? Including flower sent to remediate through extraction or only to flower that is intended to be sold in flower form?

This requirement is for all products, regardless of current form or intended form.

f. Before ordering mycotoxins testing or deciding to destroy, can growers or processors still submit for *Aspergillus* retesting like they have been able to in the past?

No, a failed Aspergillus test must be followed up with a passing mycotoxins test.

g. Can the CRA also provide a list of acceptable remediation techniques once subsequent passing results for mycotoxins are provided for a sample?

The CRA does not make recommendations on remediation techniques. If a licensee would like to discuss a remediation technique that they're interested in, the licensee should contact the CRA at CRA-Compliance@michigan.gov.

h. How will mycotoxins testing appear in Metrc?

If a package fails for *Aspergillus*, its status will remain Testing in Progress until the mycotoxins test results have been entered. Only then will a Test Failed result be pushed through.

i. Will there be any "additional-mycotoxins" test option in Metrc that can be ordered individually?

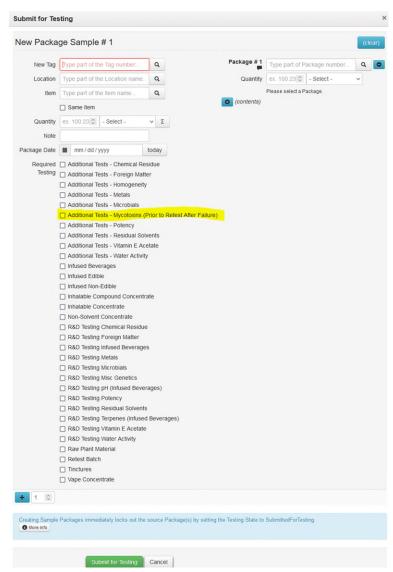
Yes.

j. When a licensee chooses to perform mycotoxins testing on a failed *Aspergillus* sample, who is responsible for scheduling the additional testing in METRC?

The licensee who owns the package is responsible for scheduling all testing required for their product(s).

k. Per the established METRC permissions, the licensee is unable to modify the testing manifest once the lab has accepted it. Will the licensee need to contact METRC to update the initial manifest with mycotoxins testing? Or will they need to create a new manifest (which would also require new testing tags) for the additional mycotoxins testing?

When the licensee is making the test sample, the action window below will show and the licensee should check the highlighted box for the additional test.



If the licensee has already made the test sample, they can just simply let the testing facility know that they need to add the additional test for the existing sample and the testing facility can enter the test results for the batch without issue.

I. What are the sample collection expectations for laboratories that are sampling for ONLY mycotoxins testing?

Each laboratory should follow their approved sampling Standard Operating Procedure (SOP).

m. Do SCFs need to collect 0.5% of the harvest batch to test for mycotoxins OR no less than 0.5g?

There is no need to collect 0.5% of the batch as it is not a full compliance panel, but rather an add-on test. To that end, the CRA requires that each laboratory write into their sampling SOP how much sample is required for mycotoxins testing. The minimum sample size for mycotoxins testing is 0.5g.

n. If a sample passes mycotoxins testing, but then fails *Aspergillus* retesting, will it require a second mycotoxins test before additional action can be taken?

Yes, each time a failed Aspergillus test is reported, a passing mycotoxins test is required before moving the product.

o. Do research and development (R&D) Aspergillus failures require mycotoxins testing?

No.

p. Do R&D mycotoxins failures require the batch to be destroyed?

No.

q. If flower failed for *Aspergillus <u>prior</u>* to 12/1/22, is it still a requirement to test mycotoxins?

If the package failed for Aspergillus before 12/1/22 and has a status of test failed, mycotoxins testing is not required. However, if the package is retested and fails again upon retest, mycotoxins testing will be required to push the package status through to a final status.

r. Does mycotoxins testing have to be done at the original lab where the package failed *Aspergillus* testing?

No.

s. Is there any particular lab that mycotoxins testing should be done at?

No, mycotoxins testing can be done at any lab with an approved method for mycotoxins testing.

t. Should a lab collect a new sample for the mycotoxins retest?

No, mycotoxins testing can be done on the retained portion of the original sample if the laboratory selected for mycotoxins testing is the same as the one chosen for Aspergillus testing.

u. Is it possible to have a product retested if it initially fails for *Aspergillus* and then fails for mycotoxins?

Yes.

v. Is there an action limit for mycotoxins or is it pass/fail upon detection

Yes, there are action limits. The mycotoxins action limits are in the <u>Sampling and Testing</u> Guide.

w. Is it possible to complete a remediation process if the product fails for mycotoxins?

It may be possible, but it is the responsibility of the licensee to determine which methods of remediation are appropriate and effective.

x. Is there a particular way that we should destroy the product if that is the proper course of action.

Product should be destroyed according to R420.211 Marihuana product destruction and waste management.

y. What product does this process apply to?

This applies to all products that require *Aspergillus* testing that are not in a final status as of December 1st.

z. If a source batch fails for *Aspergillus* and then passes for mycotoxins but fails for *Aspergillus* again, do both retests need to test for mycotoxins?

Every failed test for Aspergillus must be followed by a mycotoxins test.

aa. If a source batch fails for *Aspergillus* and then passes for mycotoxins but fails for *Aspergillus* again, does the batch have to be destroyed, or can it be remediated and then retested?

The product may be remediated and then retested.